

What is claimed is:

1. A method for detecting tumor-derived or tumor-associated RNA in the plasma or serum fraction of blood from a human or animal, wherein the tumor-derived or tumor-associated RNA is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA or any combination thereof, the method comprising the steps of:

- extracting mammalian RNA from plasma or serum, wherein a fraction of said extracted RNA comprises a tumor-derived or tumor-specific RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA or any combination thereof;
- amplifying or signal amplifying said fraction of the extracted RNA or corresponding cDNA prepared therefrom, wherein amplification is performed in either a qualitative or quantitative fashion using primers specific for the tumor-derived or tumor-associated RNA or cDNA corresponding thereto to produce an amplified product; and
- detecting the amplified product produced from the RNA or cDNA.

20 2. A method for detecting extracellular tumor-derived or tumor-associated RNA in a bodily fluid from a human or animal, wherein the tumor-derived or tumor-associated RNA is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA,

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c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA or any combination thereof, the method comprising the steps of:

- a) extracting mammalian RNA from a bodily fluid, wherein a fraction of said extracted RNA comprises an extracellular tumor-derived or tumor-specific RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA or any combination thereof;
- b) amplifying or signal amplifying said fraction of the extracted RNA or cDNA corresponding thereto, wherein amplification is performed in either a qualitative or quantitative fashion using primers or probes specific for the tumor-derived or tumor-associated RNA or cDNA corresponding thereto to produce an amplified product; and
- c) detecting the amplified product produced from the RNA or cDNA corresponding thereto.

15 3. The method of claim 1, wherein the amplification in step (b) is performed by a RNA amplification method that amplifies the RNA directly or wherein the RNA is first reverse transcribed to cDNA whereby the cDNA is amplified, and wherein the amplification method is reverse transcriptase polymerase chain reaction, ligase chain reaction, branched DNA signal amplification, amplifiable RNA reporters, Q-beta replication, transcription-based amplification, isothermal nucleic acid sequence-based amplification, self-sustained sequence replication assay, boomerang DNA amplification, strand displacement activation, or cycling probe technology.

35 4. The method of claim 2, wherein the amplification in step (b) is performed by a RNA
40 amplification method that amplifies the RNA directly or wherein the RNA is first reverse
45 transcribed to cDNA whereby the cDNA is amplified, and wherein the amplification
50 method is reverse transcriptase polymerase chain reaction, ligase chain reaction,
55 branched DNA signal amplification, amplifiable RNA reporters, Q-beta replication,
60 transcription-based amplification, isothermal nucleic acid sequence-based amplification,
65 self-sustained sequence replication assay, boomerang DNA amplification, strand
70 displacement activation, or cycling probe technology.

75 5. The method of claim 1, wherein detection of the amplified product in step (c) is
80 performed using a detection method that is gel electrophoresis, capillary electrophoresis,
85 ELISA detection including using biotinylated or other modified primers, labeled
90 fluorescent or chromagenic probes, laser-induced fluorescence, Southern blot analysis,
95 Northern blot analysis, electroluminescence, reverse blot detection, or high-performance
100 liquid chromatography.

105 6. The method of claim 2, wherein detection of the amplified product in step (c) is
110 performed using a detection method that is gel electrophoresis, capillary electrophoresis,
115 ELISA detection including using biotinylated or other modified primers, labeled
120 fluorescent or chromagenic probes, laser-induced fluorescence, Southern blot analysis,
125 Northern blot analysis, electroluminescence, reverse blot detection, or high-performance
130 liquid chromatography.